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Knodel

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(54) **STAPLER CARTRIDGE WITH STAPLES FRANGIBLY AFFIXED THERETO**

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A61B 17/064 (2006.01)

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USPC **227/176.1**; 227/19; 606/219

(58) **Field of Classification Search**
USPC 227/175.1–182.1, 19, 901, 902; 606/219
See application file for complete search history.

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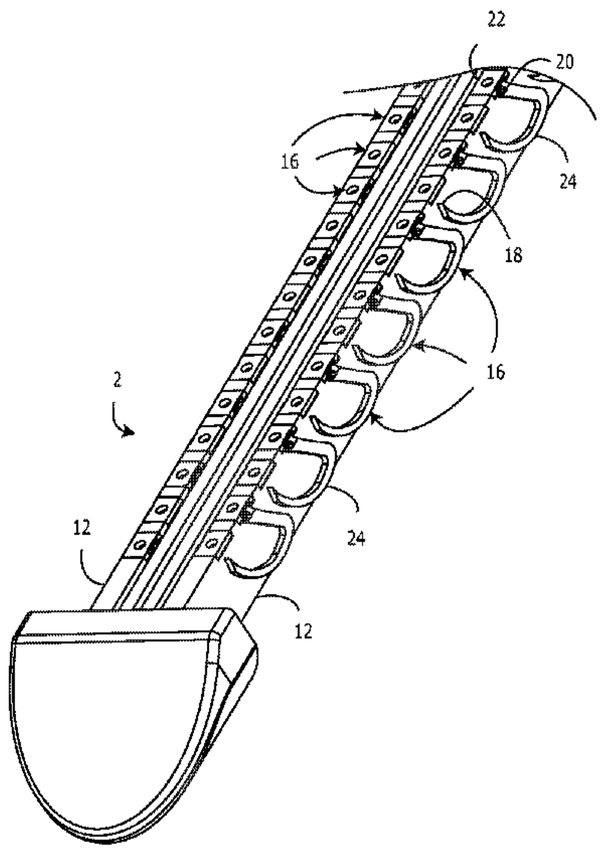
(57) **ABSTRACT**

A surgical apparatus may include a cartridge, and surgical staples affixed to and frangibly separable from that cartridge. A method for surgical stapling utilizing that apparatus may include providing at least one wedge; and moving at least one wedge into the cartridge, where that moving deforms and then shears from the cartridge at least one staple. A method of manufacturing an apparatus for use with a surgical stapler may include fabricating a cartridge configured to be received by the surgical stapler; fabricating staples; and fixing the staples to the cartridge.

11 Claims, 4 Drawing Sheets



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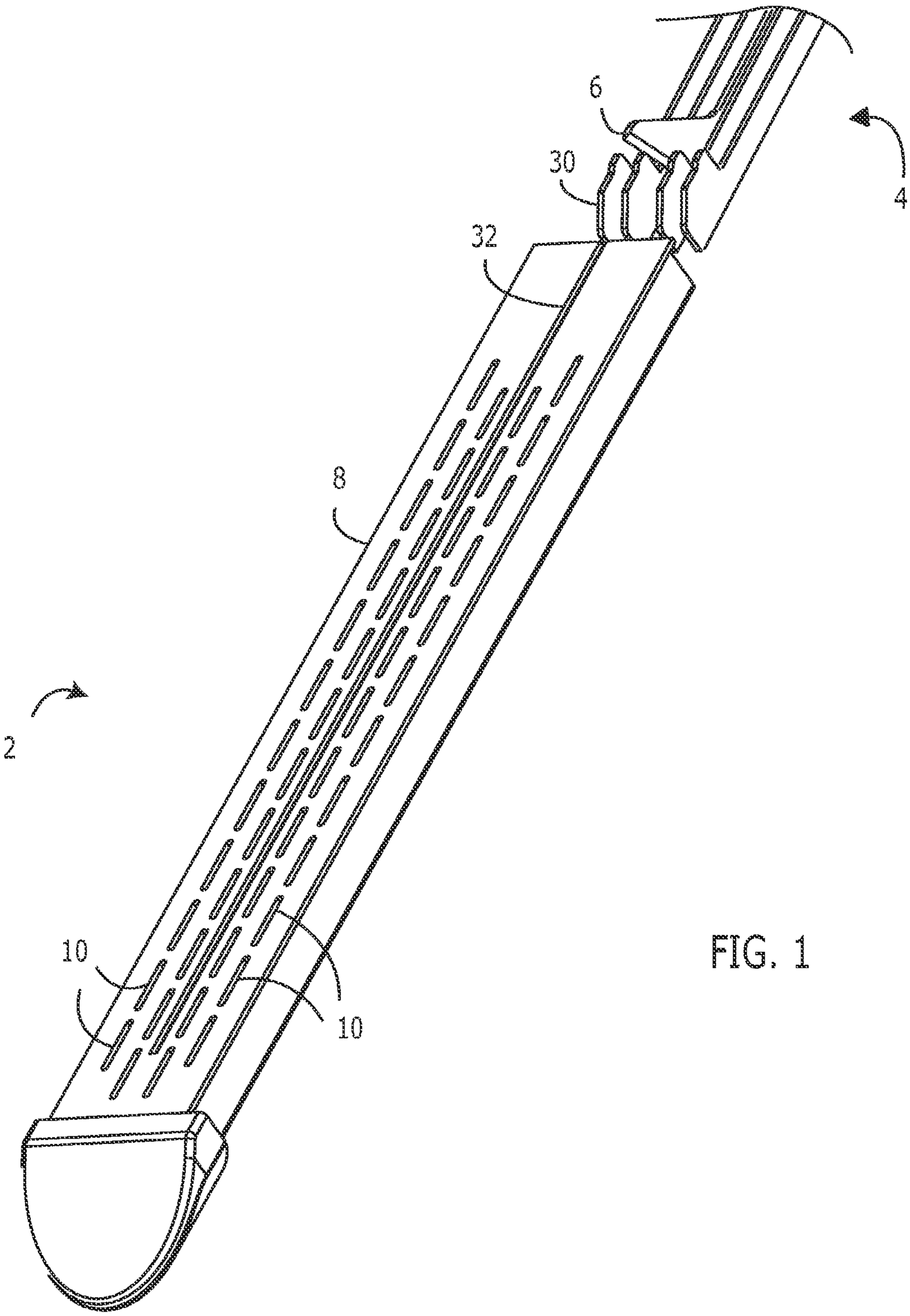

FIG. 1

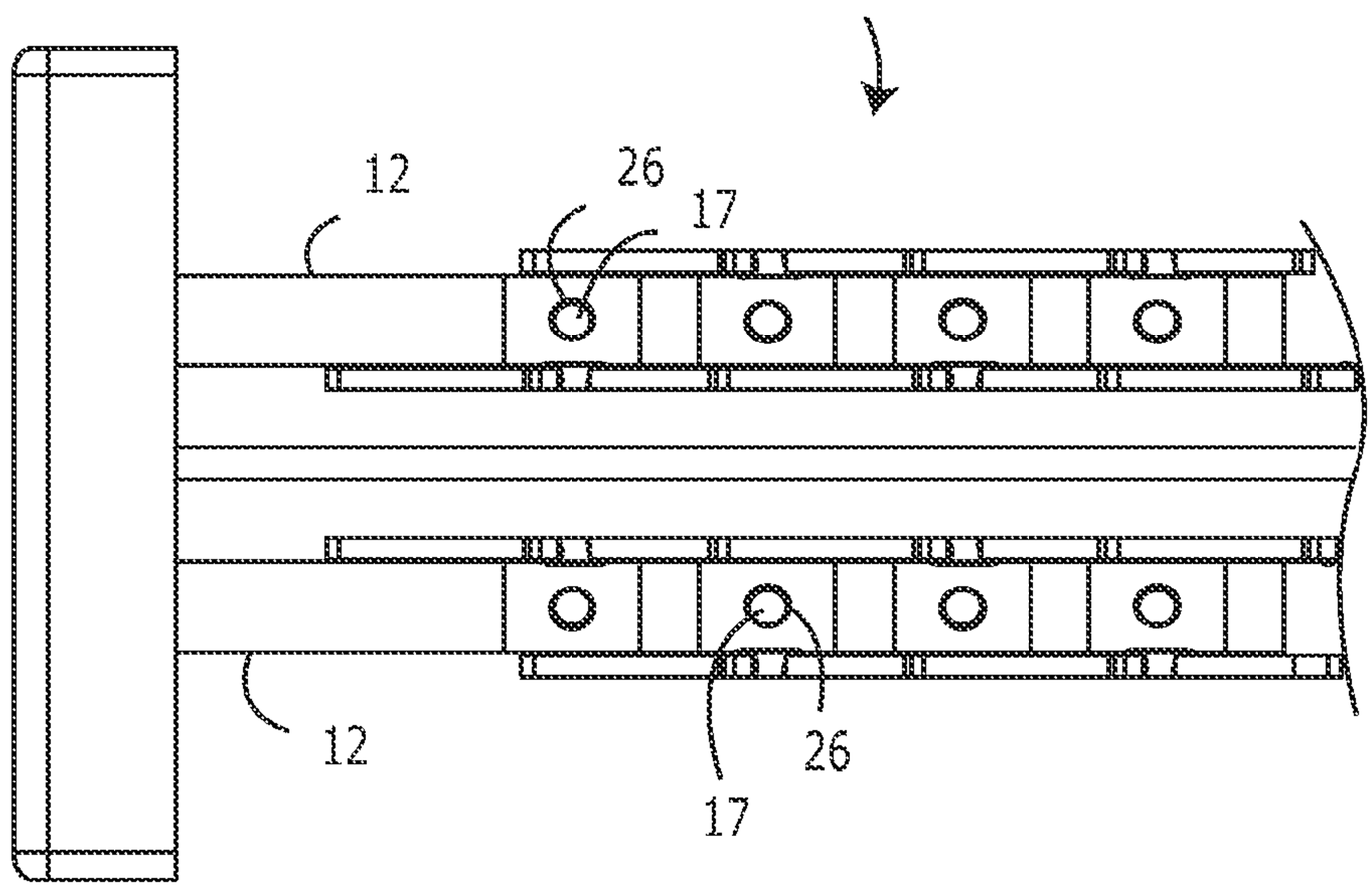

FIG. 2

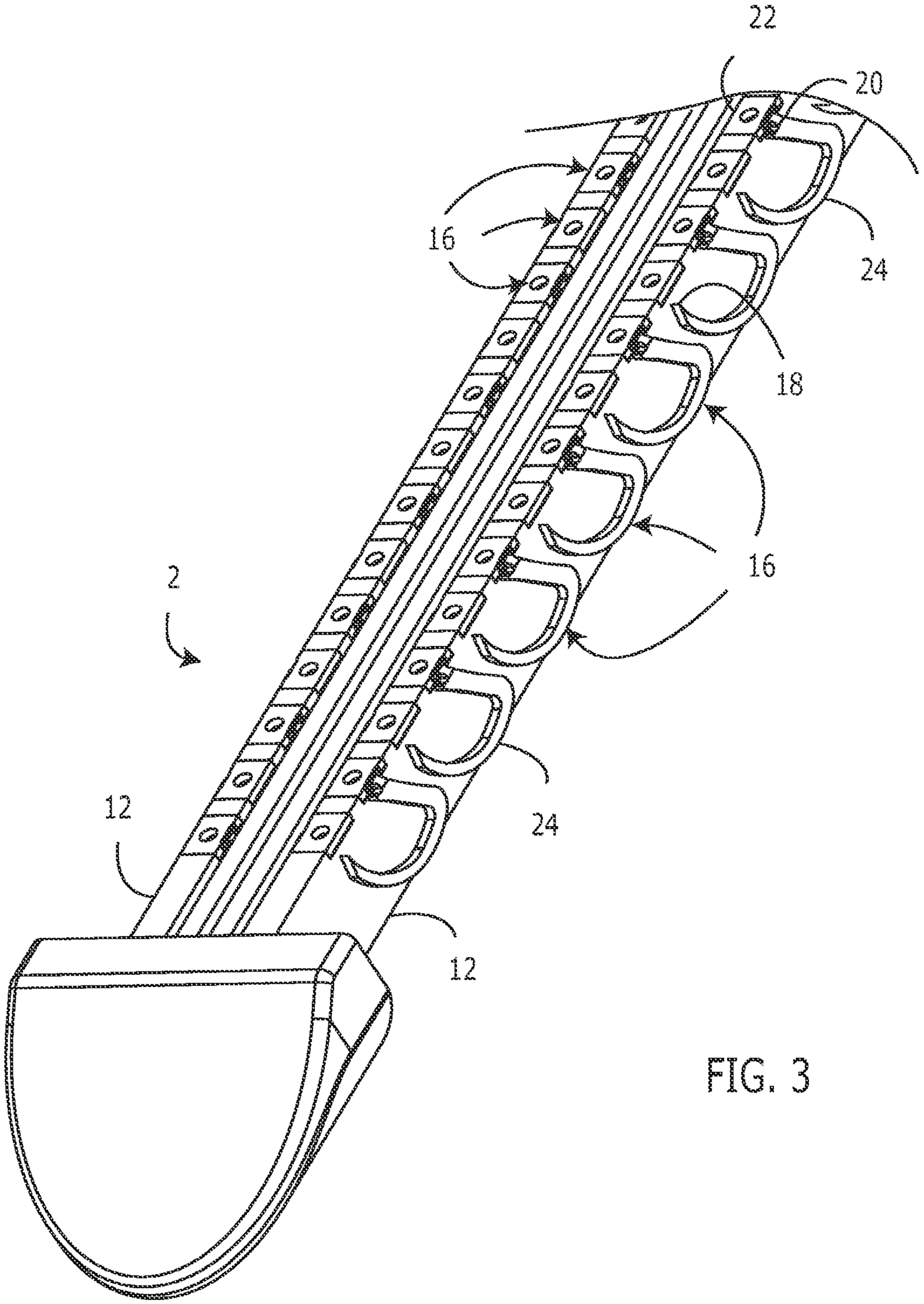

FIG. 3

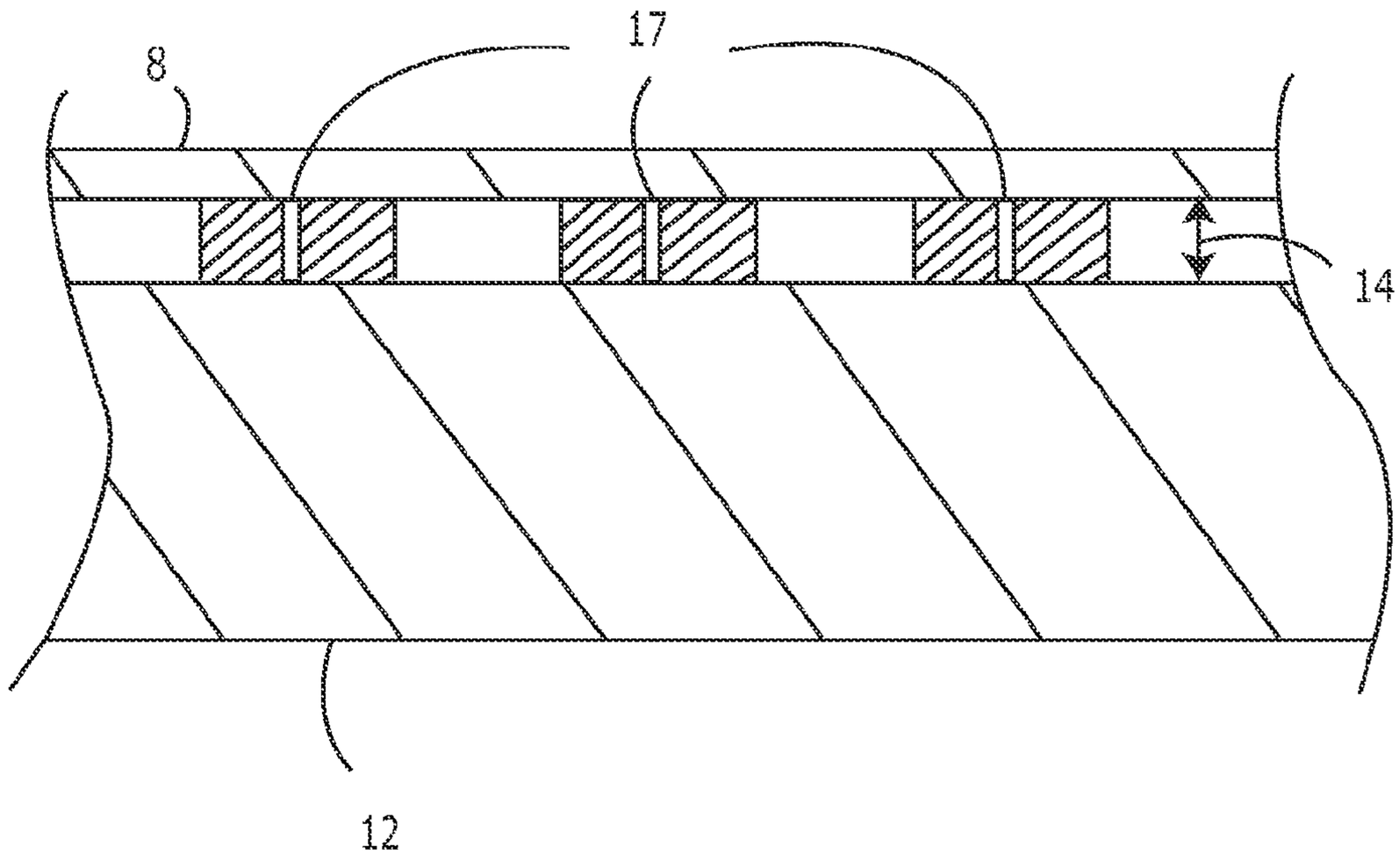

FIG. 4

STAPLER CARTRIDGE WITH STAPLES FRANGIBLY AFFIXED THERETO

CROSS REFERENCE TO RELATED APPLICATIONS

The present application is a divisional of copending application Ser. No. 12/683,382, filed Jan. 6, 2010, and priority is hereby claimed under 35 U.S.C. §120.

FIELD OF THE INVENTION

The invention generally relates to surgical staplers and stapling.

BACKGROUND

An endocutter is a surgical tool that staples and cuts tissue to transect that tissue while leaving the cut ends hemostatic. An endocutter is small enough in diameter for use in minimally invasive surgery, where access to a surgical site is obtained through a trocar, port, or small incision in the body. A linear cutter is a larger version of an endocutter, and is used to transect portions of the gastrointestinal tract. A typical endocutter receives at its distal end a disposable single-use cartridge with several rows of staples, and includes an anvil opposed to the cartridge. The staples may be held in individual pockets, with staple drivers underneath each staple. As a wedge advances into the cartridge, that wedge sequentially pushes a number of staple drivers upward, and the staple drivers in turn both linearly push each corresponding staple upward out of its pocket, deforming it against an anvil. The manufacturing process required to place those small individual staples and staple drivers in the corresponding small pockets is difficult, and the number of parts involved complicates the system and requires a minimum size of cartridge that may be larger than optimally desired.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a perspective view of an exemplary cartridge and exemplary wedge assembly.

FIG. **2** is a top cutaway view of the exemplary cartridge of FIG. **1**.

FIG. **3** is a perspective cutaway view of the exemplary cartridge of FIG. **1**.

FIG. **4** is a side cross-section view of the exemplary cartridge of FIG. **1**, with staples omitted for clarity.

The use of the same reference symbols in different figures indicates similar or identical items.

DETAILED DESCRIPTION

U.S. patent application Ser. No. 12/400,790, filed Mar. 9, 2009, entitled the "Feeder Belt Document," is hereby incorporated herein by reference in its entirety. The Feeder Belt Document describes exemplary feeder belts used in a surgical stapler, to which a plurality of staples are frangibly connected. Because new staples are fed to an end effector of a surgical stapler by the feeder belts for sequential deployment, the surgical stapler of the Feeder Belt Document does not need or utilize a plurality of single-use cartridges in order to deploy multiple sets of staples.

As is commonly used in the medical device industry, particularly in the surgical stapler business, the term "cartridge" means, and is expressly defined in this document to mean, a portion of a surgical stapler that holds at least one staple, and

that is insertable within and releasably connected to a remainder of the surgical stapler. Referring to FIG. **1**, an exemplary cartridge **2** is shown, along with an exemplary wedge assembly **4** and knife **6**. The cartridge **2** may be utilized in conjunction with any surgical stapler that is capable of receiving it, and that includes at least a wedge assembly **4** capable of moving into the cartridge **2** to deploy staples (as described in greater detail below) and then moving out of the cartridge **2** to allow the spent cartridge **2** to be removed from the surgical stapler. The cartridge **2** may be received in a remainder of a surgical stapler in any suitable manner, such as by a pressure fit or interference fit; passively or affirmatively; or in any other suitable manner. The cartridge **2** may be received at the distal end of a remainder of the surgical stapler, and/or along the side of a remainder of the surgical stapler. The cartridge **2** may be useful in conjunction with an articulated surgical stapler having an articulation proximal to the location at which the cartridge is attached to the stapler. Such an articulation may be, for example, as described in U.S. patent application Ser. No. 12/400,760, filed Mar. 9, 2009, or in U.S. patent application Ser. No. 12/612,614, filed Nov. 4, 2009, both of which are hereby incorporated herein by reference in their entireties.

The cartridge **2** may be shaped in any suitable manner. As one example, the cartridge **2** may include an upper surface **8**. The upper surface **8** may be generally flat, and generally rectangular. However, the upper surface **8** need not be generally flat along all or part of its area, and may be shaped in a manner other than rectangular. Further, the upper surface **8** need not be a discrete part of the cartridge **2**, and instead simply may be a portion of a larger surface or area of the cartridge **2**. The upper surface **8** of the cartridge **2** may include a plurality of openings **10** defined completely therethrough. As described in greater detail below, each opening **10** may be aligned with a corresponding staple, such that a staple may be deployed through each opening **10**. Each opening **10** may be generally longitudinally-oriented, and generally rectangular in shape. Alternately, the orientation and/or shape of at least one opening **10** may be different. The openings **10** may be organized into one or more generally-longitudinally-oriented rows, corresponding to the locations of staples in the cartridge **2**. As another example, the openings **10** may be interconnected to form one or more larger openings, such that more than one staple may be deployed through a single opening **10**. Alternately, the upper surface **8** may be omitted altogether, thereby rendering openings **10** superfluous.

Referring also to FIGS. **2-4**, the cartridge **2** also may include one or more rails **12**. The rails **12** may be oriented generally longitudinally, and may be shaped generally as rectangular solids. At least one rail **12** may be dimensioned greater in lateral width than in vertical height, as seen most clearly in FIG. **3**. As another example, at least one rail **12** may be oriented and/or shaped in any other suitable manner. The rails **12** may be spaced laterally apart from one another. The rails **12** may be fabricated from any suitable material, and in any suitable manner. At least one rail **12** may be vertically spaced apart from the upper surface **8** of the cartridge **2** by a gap **14**. One or more pins **17** may extend from at least one rail **12** across the gap **14** to the upper surface **8**. The pins **17** may be fabricated integrally with the corresponding rail **12** and/or upper surface **8**, or may be fabricated separately and later connected thereto. At least one pin **17** may be generally cylindrical in shape. However, at least one pin **17** may be shaped differently. The pins **17** advantageously are shaped the same as one another, but at least one pin **17** may be shaped differently than at least one other pin **17**.

A plurality of staples **16** may be affixed to and frangibly separable from the cartridge **2**. The staples **16** may be shaped substantially in the same manner as the staples described in the Feeder Belt Document, or may be shaped in any other suitable manner. Each staple **16** may have a free end **18**, and an opposite end **20** that is connected to a stem **22**. The portion of the staple **16** between the free end **18** and the opposite end **20** may be referred to as the tine **24**. The stem **22** of at least one staple **16** may be substantially perpendicular to the tine **24** of that staple **16**. As another example, the stem **22** and tine **24** of a staple **16** may be oriented at a different angle to one another. The stem **22** may be substantially planar and rectangular, but may be shaped differently if desired. Each tine **24** may be fixed to the corresponding stem **22**. Advantageously, the tine **24** and corresponding stem **22** are integral, and may be fabricated by stamping a piece of flat sheet metal, then bending the tine **24** and the stem **22** to the desired angle relative to one another. Advantageously, each staple **16** is positioned on a corresponding rail **12**, such that the stem **22** is positioned on top of that rail **12**. The thickness of the stem **22** may be substantially the same as the height of the gap **14** between each rail **12** and the upper surface **8**. Alternately, the thickness of at least one stem **22** may be less than the height of the gap **14** between each rail **12** and the upper surface **8**. Each staple **16** may be fixed to the upper surface **8** of the cartridge and/or to a rail **12**, in any suitable manner. As one example, at least one stem **22** may include at least one aperture **26** defined therethrough. That aperture **26** may receive a corresponding pin **17** that extends from the upper surface **8** to a rail **12**. As another example, at least one stem **22** may be welded to the top of a corresponding rail **12** and/or to the bottom of the upper surface **8**. As another example, at least one stem may be affixed to the top of a corresponding rail **12** and/or to the bottom of the upper surface **8** by adhesive. As another example, at least one stem **22** may be pressure-fit between the upper surface **8** and the corresponding rail **12**. As another example, at least one stem **22** may be fixed to a corresponding rail **12** and/or the upper surface **8** in two or more ways, such as, for example, by welding and by receiving a pin **17** through an aperture **26** in the stem **22**. At least one staple **16** may be fabricated separately from a remainder of the cartridge **2**, then affixed to the cartridge **2** as set forth above. Alternately, at least one staple **16** may be integral with a remainder of the cartridge **2**.

The staples **16** may be arranged in the cartridge **2** in any suitable manner. As one example, one or more staples **16** may be arranged against a corresponding rail **12**, with each stem **22** fixed to the corresponding rail **12**. The staples **16** may be arranged relative to the rail **12** and to one another such that the tine **24** extending from a particular staple **16** is positioned on one lateral side of the rail **12**, and the tine **24** extending from each longitudinally-adjacent staple **16** is positioned on the other lateral side of the rail **12**. In this way, the tines **24** alternate sides relative to the rail **12** longitudinally along the rail **12**, as seen most clearly in FIGS. **2-3**. As another example, each staple **16** may include a single stem **22**, with two tines **24** extending from it. Each tine **24** may extend from a lateral side opposed to the other. The stem **22** may be positioned on top of a rail **12**, with each stem **22** fixed to the corresponding rail **12**, and with each tine **24** positioned on a different lateral side of the corresponding rail **12**. One tine **24** may be positioned longitudinally distal to the other tine **24** extending from the same stem **22**. Such staples **16** may be arranged relative to the rail **12** such that the tines **24** alternate sides relative to the rail **12** longitudinally along the rail **12**. As another example, at least one staple **16** is integral with the upper surface **8**, and is affixed to a remainder of the upper surface **8** at the end **20** of the tine **24**. In such a configuration, the staple **16** may be fabricated by punching, stamping, or otherwise dislodging it from the upper surface **8**, such that the staple **16** extends from one end of a corresponding opening **10** in the upper surface **8**, and the opening **10** results from the fabrication of the staple **16** associated with it. Further, in such a configuration, the stem **22** may be omitted from the staple **16**. Regardless of the particular configuration of the staples **16**, each tine **24** may be positioned adjacent to a corresponding opening **10** in the upper surface **8**, and/or may be affixed to the upper surface **8** in proximity to the corresponding opening **10**.

At least part of each staple **16** may be frangibly affixed to a remainder of the cartridge **2**. "Frangibly affixed" is defined to mean that at least part of each staple **16** is fixed to a remainder of the cartridge **2** in such a manner that it must be sheared or otherwise broken off from a remainder of the cartridge **2** to be removed therefrom. As one example, at least one staple **16** may be frangible at the junction between the stem **22** and the tine **24**. Such a junction may have a weakened area to facilitate frangibility. As another example, at least one staple **16** may remain intact during deployment, and the stem **22** of the staple **16** is frangible from the corresponding rail **12** and/or the upper surface **8**. As another example, where the tine **24** is integral with the upper surface **8**, the tine **24** may be frangible at the junction between the tine **24** and the upper surface **8**.

The cartridge **2** may be actuated, and the staples **16** deployed, substantially as set forth in the Feeder Belt Document, with the following general differences. The wedge assembly **4** includes one or more wedges **30** configured generally as set forth in the Feeder Belt Document. Initially, the wedge or wedges **30** may be positioned proximal to the cartridge **2**. In this way, the wedge or wedges **30** do not interfere with the insertion of the cartridge **2** into a remainder of the surgical stapler. The cartridge **2** may be inserted into the stapler, or may already be present in the stapler, prior to actuation of the stapler. The wedge assembly **4** is moved distally, advantageously by sliding. As the wedge assembly **4** moves distally, it slides the wedge or wedges **30** distally as well. Advantageously, one wedge **30** slides along a corresponding row of staples **16** to sequentially deform staples **16** outward through the corresponding openings **10** in the upper surface **8**, and then break staples **16** from the cartridge **2**. Such deformation and later breakage of the staple may be as set forth generally in the Feeder Belt Document. As one example, the stem **22** of one or more staples **16** is held substantially in place by its affixation to a corresponding rail **12** and/or to the upper surface **8**, as set forth above. As a wedge **30** slides distally relative to the staple **16**, the wedge **30** first engages the tine **24** of that staple **16**, causing the tine **24** to move upward and to rotate about the junction between the tine **24** and the stem **22**. Rotation of the tine **24** upward causes the tine **24** to move up through a corresponding opening **10** in the upper surface **8**, through tissue, and then move into contact with an anvil (not shown), such as set forth in the Feeder Belt Document. Contact between the tine **24** and the anvil deforms the tine **24** to its closed configuration. As the wedge **30** continues to move distally relative to the staple **16**, both the wedge **30** and the tine **24** may be shaped such that the wedge **30** may continue to contact and exert force on the tine **24** after the tine **24** has been deformed. This force increases until the tine **24** is broken, sheared or otherwise separated from the stem **22**. As another example, this force increases until the stem **22** is broken, sheared or otherwise separated from a remainder of the cartridge **2**, such as from a corresponding rail **12** and/or the upper surface **8** of the cartridge **2**. The wedge **30** thereby may sequentially separate the frangible staples **16** from a remainder of the cartridge **2**.

A knife **6** also may be connected to the wedge assembly **4**, and may slide upward through the corresponding knife slot **32** in the upper surface **8** as the wedge assembly **4** moves distally through the cartridge **2**. The knife **6** may be actuated, and may cut tissue, substantially as set forth in the Feeder Belt Document. Optionally, the knife **6** may be omitted from the wedge assembly **4**, if desired. The knife **6** may be configured to move into the cartridge **2**, then move upward through and out of the knife slot **32**, then slide along the knife slot **32**, then move downward through the knife slot **32**. In this way, the knife **6** may be held in a position in which it does not extend through the knife slot **32** both before and after it has cut tissue, in order to enhance safety for the user and the patient.

After the wedge assembly **4** has been actuated to deploy one or more of the staples **16**, the cartridge **2** is spent. The wedge assembly **4** then may be retracted proximally through and then out of the proximal end of the cartridge **2**. The spent cartridge **2** then may be removed from a remainder of the surgical stapler. If desired, a new cartridge **2** may then be inserted into the surgical stapler in place of the previous, spent cartridge **2**. The new cartridge **2** may be actuated substantially as described above.

While the invention has been described in detail, it will be apparent to one skilled in the art that various changes and modifications can be made and equivalents employed, without departing from the present invention. It is to be understood that the invention is not limited to the details of construction, the arrangements of components, and/or the method set forth in the above description or illustrated in the drawings. Statements in the abstract of this document, and any summary statements in this document, are merely exemplary; they are not, and cannot be interpreted as, limiting the scope of the claims. Further, the figures are merely exemplary and not limiting. Topical headings and subheadings are for the convenience of the reader only. They should not and cannot be construed to have any substantive significance, meaning or interpretation, and should not and cannot be deemed to indicate that all of the information relating to any particular topic is to be found under or limited to any particular heading or subheading. Therefore, the invention is not to be restricted or limited except in accordance with the following claims and their legal equivalents.

What is claimed is:

1. A method for surgical stapling, the method comprising:
providing a cartridge and a plurality of surgical staples affixed to and frangibly separable from said cartridge, the plurality of surgical staples arranged in a row along a rail of the cartridge, wherein a stem of a staple of the plurality of surgical staples is fixed to the rail by a pin received through an aperture of the stem, the pin extending across a gap to one of the rail or an upper surface of the cartridge;
providing at least one wedge; and
moving said at least one wedge into said cartridge, the moving being collinear with the row, wherein said moving deforms and then shears from said cartridge at least one of said plurality of surgical staples.

2. The method of claim **1**, further comprising:
providing a surgical stapler;
inserting said cartridge into said stapler before said moving; and
removing said cartridge from said surgical stapler after said moving.

3. The method of claim **1**, wherein the at least one wedge has an inclined surface that moves collinearly along the row.

4. The method of claim **1**, wherein the plurality of surgical staples are affixed to an outer surface of a longitudinal rail extending within the cartridge.

5. A method for surgical stapling, comprising:
providing a cartridge having a plurality of surgical staples affixed to and frangibly separable from a surface of a longitudinal rail of the cartridge, the plurality of surgical staples arranged in a row along the surface, wherein a stem of a staple of the plurality of surgical staples is fixed to the rail by a pin received through an aperture of the stem, the pin extending across a gap to one of the rail or an upper surface of the cartridge; and
moving a wedge into the cartridge, the moving being collinear with the row, wherein said moving deforms and then shears from said cartridge at least one of said plurality of surgical staples.

6. The method of claim **5**, wherein each surgical staple of the plurality of surgical staples has a first end and a second end, the first end affixed to the stem, the stem affixed to a top surface of the rail, and wherein the second end is below a plane defined by the first end of each of the plurality of surgical staples.

7. The method of claim **5**, wherein the cartridge includes a plurality of longitudinal rails and a plurality of wedges.

8. The method of claim **6**, wherein the stem is affixed to the pin extending from the top surface of the rail.

9. The method of claim **7**, wherein one wedge is dedicated to one of the plurality of longitudinal rails.

10. The method of claim **5**, wherein the wedge has an inclined surface and wherein a surface of the staple slides along the inclined surface during the moving.

11. The method of claim **10**, wherein the inclined surface contacts multiple surgical staples contemporaneously.

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